No. 92-102

In The

Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually, and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

vs.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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CORPORATE AFFILIATIONS OF RESPONDENT

Respondent, Merrell Dow Pharmaceuticals, Inc., is a wholly-owned subsidiary of Marion Merrell Dow Inc., which is approximately two-thirds owned by The Dow Chemical Company. Their subsidiaries and affiliates which have securities in the hands of the public are the following:

Arabian Chemical Company Limited

Compagnie des Services Dowell Schlumberger S.A

DCU/LB TRUST

Destec Energy, Inc.

Dexco Polymers

Dow Chemical Iberica S.A.

Transformadora De Etileno S.A.

Chimtrade

Crestar Energy Inc.

Dowell Schlumberger Canada Incorporated

Fort Saskatchewan Ethylene Storage Limited Partnership

U.D. Tech Inc.

Wabiskaw Explorations Ltd.

Cromarty Petroleum Company Limited

Petroquimica-Dow S.A.

Ulsan Pacific Chemical Corporation

Expoxital S.R.L.

Safechem Umwelt Service GmbH

DowBrands L.P.

Dow Corning Corporation

Dowell Schlumberger Corporation

Dowell Schlumberger Inc.

Fort Saskatchwan Ethylene Storage Corporation

Promix System

Dow Kakoh Kabushiki Kaisha

Dow Mitsubishi Kasei Limited

Anticorrosivos Industriales Limitada

Family Comercio e Industria de Produtos de Limpeza Ltda.

Dow-United Technologies Composite Products Inc.

El Dorado Terminals Company

Gurit-Essex A.G.

Etoxilados del Plata S.A.

Joliet Marine Terminal Trust Estate

Lucky Epoxy Limited

Marion Merrell Dow K.K.

MDP (Holdings) Ltd.

Tanabe / Marion Partnership

P.T. Pacific Indomas Plastic Indonesia

Airco Generon Systems LP

DH Compounding Company

DowElanco

Dow Elanco B.V.

Elanco Ihara K.K.

P.T. Pacific Chemicals Indonesia

Pacific Chemicals Berhad

Generon Systems

Generon Systems A.G.

Scotdril Offshore Company

SD Group Service Company Limited

Siam Styrene Monomer Company Limited

Siam Synthetic Latex Company Limited

Zhejiang Pacific Chemical Corporation

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Brent, Bendectin Our Most Famous Tortogen-Litogen And The Best Studied Human Non-teratogen, 37 Teratology 447 (1988) 4

Cleary, Preliminary Notes on Reading the Rules of Evidence, 57 Neb L. Rev. 908 (1978) 16

Green, Expert Witness and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation, 86 Northwestern University Law Review 643 (1992) 5, 6,

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Lock, "the State of Peer Review", Peer Review and Scientific Publishing, Council of Biology Editors, Inc., p. 30 (1990) 25

Lock, A Difficult Balance, Editorial Peer Review in Medicine (1985) 26

Relman, "How Good Is Peer Review", New England Journal of Medicine, Vol. 321, No. 12, p. 827 25

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INTRODUCTION

Persistence in the pursuit of righteousness is a virtue; in the pursuit of heresy, it is obstinacy. Via their Petition, Petitioners join a long line of litigants who have repeatedly and unsuccessfully invited this Court to overturn the teaching *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) (*"Frye"*), and its progeny which protect judicial factfinders from scientific shamans who, in the guise of their purported expertise, are willing to testify to virtually any conclusion to suit the needs of the litigant with resources sufficient to pay their retainer.[1]

In the opinion below ("Opinion"),[2] the Ninth Circuit Court of Appeals, per Circuit Judge Kozinski, rejected the Petitioners' pleas to be permitted to swim upstream against an overwhelming scientific torrent of consensus that Bendectin does not cause limb reduction birth defects, and affirmed the granting of the motion for summary judgment made by Respondent Merrell Dow Pharmaceuticals Inc. ("Merrell Dow.") As it has consistently in the past, not only in the context of the Bendectin litigation, but in others as well, this Court should deny the Petition simply because the rule in *Frye* protects the process from becoming a spectacle in which paid experts are willing to mouth any expedient phrase,

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1. Petitions for certiorari denied raising similar issues are: *In Re: Agent Orange Product Liability Litigation*, 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub. nom Lombardi v. Dow Chemical Co.*, 487 U.S. 1234 (1988); *Brock v. Merrell Dow Pharmaceuticals. Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S.Ct. 1511 (1990) (*"Brock"*); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989) (*"Richardson"*); *In Re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990), *cert. denied*, 111 S.Ct. 1584 (1991); *Ealy v. Richardson-Merrell Inc.*, 897 F.2d 1159 (D.C. Cir. 1990), *cert. denied*, 111 S.Ct. 370 (1990) (*"Ealy"*); *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106 (15th Cir. 1991) (per curiam), *cert. denied*, 112 S.Ct. 1280 (1991).

2. *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 951 F.2d 1128 (9th Cir. 1991).

without regard to universally recognized scientific truths. In any event, review of this case is not appropriate, since under *Frye* or any other standard, Petitioners' motion would be denied, and the result would therefore be the same.

As Petitioners point out, this Court just rejected a similar invitation to abandon *Frye* in *Christophersen v. Allied Signals Corp.*, 939 F.2d 1106 (5th Cir. 1991) (per curiam) *cert. denied*, 112 S.Ct. 1280 (1991). The Fifth Circuit Court of Appeals considered, *en banc*, whether plaintiff's expert affidavit, opposing a motion for summary judgment, was admissible to support allegations that a fatal malignancy was proximately caused by workplace exposure to allegedly dangerous chemicals used in the manufacture of nickel/cadmium batteries. *Id.* at 1108. The *Christophersen* majority correctly concluded that plaintiff's expert, Dr. Miller, had nothing more than a scientific hunch, shared by no other experts in the field, and unsupported by epidemiological investigation, live animal testing, or *in vitro* testing. *Id.* at 1115. Notwithstanding the sharp division among the circuit judges of the Fifth Circuit, this Court denied review over the dissent of Justice White, joined by Justice Blackmun.[3]

In a Bendectin case, the reasons for denying Supreme Court review are infinitely more convincing than in *Christophersen*. Bendectin, an anti-nausea medicine prescribed for use during pregnancy, is perhaps the most thoroughly investigated drug in history, at least with respect to whether it causes limb reduction birth defects. As the Opinion noted, and as Petitioners do not dispute, thirty published studies, involving over 130,000 patients,

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3. If the passion of the debate among members of an *en banc* panel of a Circuit Court of Appeals positively correlates with a reason for granting a petition for certiorari, as Petitioners imply, then this Petition presents no reason for it to be granted. Indeed, on the Petitioners' Application for Rehearing, and their suggestion for rehearing *en banc*, not a single active judge requested a vote. Nor was any dissent filed to Circuit Judge Kozinski's Opinion. *See* Appendix C to Petition.

have concluded that there is no epidemiological evidence supporting a statistically significant association between Bendectin and birth defects. 951 F.2d 1128, 1129. Further, time and time again federal and state appellate tribunals have affirmed trial court and jury determinations that Bendectin is not a teratogen.[4]

Frye aside, this case is particularly inappropriate for review, since no matter what evidentiary standard is applied, the outcome would be the same. Note that the Opinion expressly states that the Third Circuit Court of Appeals declines to follow *Frye* in the context of a Bendectin case, citing *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d. 941, 955 (3d. Cir. 1990).[5] In *DeLuca III*, the trial judge followed a different standard articulated by the Third Circuit and on remand granted summary judgment to Merrell Dow, holding that plaintiffs' evidence failed to pass the applicable test of admissibility. While there arguably may be a difference in the Circuits as to the standards governing the admission of expert testimony, that issue should not be resolved here, since plaintiffs' evidence on Bendectin is inadmissible under any standard.

Simply put, the heresy advanced by this Petition is that judges and juries should be permitted by the law of evidence to render judgments or verdicts which contradict scientific propositions as

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4. *See Brock; Richardson; Lynch v. Merrell-National Labs.*, 830 F.2d 1190 (1st Cir. 1987); *Ealy; Wilson v. Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149 (10th Cir. 1990); *Turpin v. Merrell Dow Pharmaceuticals*, 736 F.Supp. 737 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir. 1992) *petition for cert. filed; Lee v. Richardson - Merrell. Inc.*, 772 F.Supp. 1027 (W.D. Tenn. 1991), *aff'd in unreported decision*, 91-5369 (6th Cir. April 22, 1992); *petition for cert. filed.*

5. Three reported decisions comprise the reported history of this litigation. For the convenience of the Court, the opinions shall be referred to hereafter as: *"DeLuca I": DeLuca v. Merrell Dow Pharmaceuticals Inc.*, 131 F.R.D. 71 (D.N.J. 1990); *"DeLuca II": DeLuca v. Merrell Dow Pharmaceuticals. Inc.*, 911 F.2d 941 (3rd. Cir. 1990); and *"DeLuca III": DeLuca v. Merrell Pharmaceuticals, Inc.*, __ F.Supp. __, 1992 WL 94064 (D.N.J.)

elementary, and as widely accepted as the laws of gravity. *Frye* and the *Federal Rules of Evidence* safeguard the judicial process from such absurd results, and it is proper that they do so. This Petition, like the many others before it, should be denied.

STATEMENT OF FACTS

A. History of Bendectin Litigation.

This Court is no stranger to Bendectin and the litigation spawned by its widespread use to provide relief for millions of pregnant women suffering from morning sickness. Notwithstanding Merrell Dow's almost universal success in defending birth defect claims brought on behalf of children whose mothers used Bendectin during pregnancy, the tidal wave of lawsuits has swept the product from the market, denying pregnant women the only effective therapy approved by the Federal Food & Drug Administration.[6]

Aside from the "experts" paid to testify on behalf of Bendectin plaintiffs, the overwhelming consensus of the relevant scientific community is that Bendectin does not cause birth defects. In fact, this medicine has been called the best studied human non-teratogen. Brent, *Bendectin Our Most Famous Tortogen-Litogen And The Best Studied Human Non-teratogen*, 37 Teratology 447 (1988). Perhaps because of early sensationalism surrounding the suspicion that Bendectin was linked to birth defects, it has now become one of the best studied drugs of all time for use in pregnancy. Skolnick, *Key Witness Against Morning Sickness Drug Faces Scientific Fraud Charge*, 263 J.A.M.A 1468, 1469 (March

6. Indeed, the F.D.A. convened a review panel of experts to examine the scientific record and reevaluate Bendectin's safety and efficacy. Despite the controversy swirling around the drug, the panel concluded that the available data demonstrates no association between Bendectin and birth defects. Department of Health & Human Services News, No. P80-45 (October 7, 1980).

16, 1990). Although serious science has established that the Bendectin children are not victims of a teratogen, there are nevertheless casualties of the Bendectin litigation. Because the litigation drove Bendectin off the market, there is now a "significant therapeutic gap" in the treatment of one of the most frequent complications of pregnancy. Ironically, the severe nausea and vomiting that would have otherwise been treated by Bendectin occasionally leads to maternal nutritional deficiencies and nerve damage in the fetus resulting, perversely, in an increased incidence of birth defects. *Id.* at pp. 1469 and 1473.[7]

Bendectin litigation has mirrored the developing scientific agreement surrounding the use of Bendectin. Less than a handful of the more than 2,000 suits filed against Merrell Dow concerning Bendectin were resolved in plaintiff's favor.[8] The consensus arising from the epidemiological studies translated into repeated success for Merrell Dow in Bendectin cases, leading one judge to observe that the purported teratogenicity of Bendectin has been reduced to the status of a perdurable superstition by the world-wide epidemiological investigations. *Richardson v. Richardson-Merrell Inc.*, 649 F.Supp. 799, 802, n. 9 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989). Appellate courts have affirmed the exclusion of expert testimony based on unpublished, non-peer reviewed, and non-epidemiological studies leading to summary judgments and directed verdicts in favor of Merrell Dow. *Richardson*, 857 F.2d 823, 825; *Lynch v. Merrell-National Laboratories, Division of Richardson-Merrell Inc.*, *supra*, 830 F.2d 1190 (1st Cir. 1987). So persuasive is the scientific

7. The sordid history of the Bendectin litigation has been reviewed in a well documented discussion in Huber, *Galileo's Revenge*, Junk Science in the Courtroom, Chapter 7, pp. 111-129 (Basic Books 1991).

8. *See generally*, Green, *Expert Witness and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Northwestern University Law Review 643, 661-668 (1992).

case against Bendectin's alleged role in causing birth defects, that the Fifth Circuit reversed a jury verdict against Merrell Dow, and entered judgment in its favor. *Brock*.[9]

Uniqueness is the most distinguishing feature of the Bendectin litigation. As noted, no other medication intended for use in pregnancy has been so intensely studied for its alleged propensity to cause birth defects. No other series of product liability actions pits a small group of litigant-financed "experts" against a diverse group of disinterested scientific investigators who have published the work of their epidemiological studies which demonstrate a complete lack of a relationship between Bendectin and birth defects in general, and limb reduction defects in specific. The singular nature of the medicine and the litigation spawned by a collection of plaintiffs' lawyers have prompted one commentator to characterize Bendectin as *sui generis*.[10]

B. The Opinion And Its Procedural History.

Before the District Court, Merrell Dow moved for summary judgment, relying upon a showing that no epidemiological study ever performed had concluded that the use of Bendectin by pregnant women has a statistically significant association to limb reduction birth defects in their offspring. The Petitioners' experts agreed that no published study showed a statistically significant association between the use of Bendectin and limb reduction birth defects, and relied instead upon "reanalyzed" data drawn from published studies finding no association between Bendectin and birth defects, which had been twisted by Petitioners' experts to supposedly demonstrate conclusions diametrically opposed to those drawn by their original authors.

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9. The Opinion placed substantial and justifiable reliance on *Lynch*, *Richardson* and *Brock*. 951 F.2d 1128, 1131.

10. Green, *op.cit.* at p. 677.

Judge Earl B. Gilliam focused the issue correctly when he emphasized the primacy of epidemiological evidence in the absence of a scientific understanding of the cause of the birth defects at issue. That is, in the face of the overwhelming scientific concurrence based on epidemiological studies that Bendectin does not cause birth defects, so called "evidence" drawn from non-epidemiologic and non-published sources will not suffice to raise a triable issue.

The propriety of granting Merrell Dow's motion for summary judgment is reinforced when one considers that virtually all of the evidence presented by Petitioners in opposition to Merrell Dow's motion had been scrutinized by other courts which found, as did Judge Gilliam, the evidence lacking.

For example, Drs. Gross, Thiersch, Newman and Swan all presented evidence on behalf of the plaintiff in *Ealy*. In that case, the testimony of these experts was insufficient to contradict the published epidemiological data; the D.C. Circuit reversed the trial judge's denial of judgment n.o.v. and instructed it to enter judgment in Merrell Dow's favor. 897 F.2d 1159, 1164. Drs. Snodgrass and Glasser presented evidence in *Brock*. As was the case in *Ealy*, the Fifth Circuit was unpersuaded, concluding that the testimony of these experts, among others, did not aid the plaintiff in satisfying her burden of proof on causation. 884 F.2d 1066, 1077. Dr. Done's evidence, although unclear, is apparently the same that he presented in *Richardson*, *supra*, and *Lynch*, *supra*, and was most recently considered at length in *DeLuca III*. In each of these cases, Dr. Done's testimony was insufficient to either support a verdict, or raise a triable issue of fact.[11]

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11. Study of *De Luca III* is particularly instructive, since it comes to exactly the same conclusion as did Judge Gilliam, although utilizing slightly different criteria for the admissibility of expert testimony, as set forth in *United States v. Downing*, 753 F.2d 1224, 1236-1237 (3rd Cir. 1985). Under both Rule 702 and Rule 703, *Federal Rules of Evidence*, Dr. Done's testimony was excluded by Judge Brown: "Dr. Done purports to

(Cont'd)

Thus, the only unique affidavit before Judge Gilliam was that of Dr. John Palmer. Alone among Petitioners' experts, Dr. Palmer has relied upon the medical records of the plaintiff children and offers to testify that to a reasonable degree of medical certainty Bendectin caused their limb defects. Significantly, however, Dr. Palmer offered no published epidemiological data supporting his conclusions, and Judge Gilliam correctly determined that it was insufficient to raise a genuine issue of material fact with respect to causation.

In affirming the District Court, the Opinion acknowledged the intense scrutiny given to the question of the responsibility of Bendectin for limb reduction defects by the federal courts. The Opinion makes three important points: First, expert testimony based on scientific technique is admissible if it is generally accepted as a reliable technique among the scientific community, relying, ultimately, on the line of cases initiated by *Frye*. Second, unpublished and non-peer reviewed reanalysis of epidemiological studies is not admissible because it is not generally accepted by the scientific community; this is especially so when the reanalysis was generated solely for use in litigation, citing *Brock, Richardson, and Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985). Third, as was recognized by *Lynch, supra, Richardson*, and *Brock*, the constellation of Petitioners' evidence, relying as it does on animal studies, chemical studies, and epidemiological reanalysis,

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(Cont'd)
have taken the numbers he entered in the boxes on his chart from either the underlying studies themselves, or, in the articles where no calculations were made, from his own calculations. In many cases, as previously noted, this is simply not true. . . . In addition, Dr. Done specifically relied upon several types of data experts in the field would not use in forming their opinions: . . . Dr. Done thus has used data upon which no epidemiologist would rely. This is where Rules 702 and 703 intersect. As the Court of Appeals stated: 'If a study's method of data and collection is faulty, it may be that no expert would rely upon the data generated as a basis for drawing any inference about the studied subject.' *De Luca*, 911 F.2d at 955 n. 4." 1992 WL 94064, 19.

provides an insufficient foundation to allow admission of expert testimony that Bendectin caused Petitioners' injuries. Accordingly, the Ninth Circuit affirmed the granting of Merrell Dow's motion for summary judgment.

The Petitioners sought rehearing by the Panel, and by the Ninth Circuit *en banc*. The petition for rehearing was denied, and no active judge requested a vote on the suggestion for rehearing *en banc*. This Petition then followed.

C. Errors In Petition.

For purposes of satisfying the requirements of Rule 15.1, Supreme Court Rules, Merrell Dow draws to the Court's attention the following misstatements of fact in the Petition.

On the fifth page of the Petition, Petitioners state that Merrell Dow conceded the qualifications of the experts, and that one of the experts were qualified in the discipline of dysmorphology. Merrell Dow never conceded the qualifications of the Petitioners' experts, and none of the eight witnesses proffered by Petitioners were qualified in dysmorphology.

On the seventh page of the Petition, the Petitioners assert that the Ninth Circuit declined to review legal arguments concerning Rule 703, *Federal Rules of Evidence*. This statement is plainly false in light of the heavy reliance in the Opinion placed on *Lynch v. Merrell-National Laboratories. Division of Richardson-Merrell, Inc., supra*, 830 F.2d 1190, and *Richardson*, 857 F.2d 823. Both *Lynch* and *Richardson* discuss at length Rule 703, *Federal Rules of Evidence*, and accordingly the Opinion by embracing the reasoning of *Lynch* and *Richardson* did so as well.

SUMMARY OF ARGUMENT

The Petition satisfies none of the special and important reasons articulated by Rule 10.1, Supreme Court Rules, to warrant review on a writ of certiorari. This case and Bendectin litigation to date may be sufficiently unique that it cannot present a proper vehicle through which this Court can articulate legal axioms useful to litigation in other contexts. Accordingly, review by this Court would reach merely academic and episodic issues. *Rice v. Sioux City Memorial Cemetery*, 349 U.S. 70, 74 (1955).

Because of the unique posture of the Bendectin litigation, the purported split between the Circuits, as suggested by the Petition, is nothing more than a semantic abstraction, lacking any practical significance in the resolution of Bendectin cases. The Opinion transgresses no limitation on inherent judicial authority concerning the admissibility of evidence. Further, the Opinion's insistence upon the requirement for peer review is not expressed as a litmus test appropriate for the admissibility of all expert testimony, but rather is a well-considered rule, appropriately fashioned for the narrow and unparalleled circumstance out of the science underpinning the Bendectin litigation. Accordingly, the Petition should be denied.

ARGUMENT

I.

IN THE CONTEXT OF BENDECTIN LITIGATION, ALL CIRCUIT COURTS OF APPEAL REQUIRE THAT EXPERT TESTIMONY SATISFY A THRESHOLD OF RELIABILITY.

The Petition's suggestion of a schism between the Circuit Courts of Appeal on the application of the *Frye* standard is an inquiry better addressed by philology than jurisprudence. In

Bendectin litigation, where the disinterested scientific community universally agrees that Bendectin does not cause limb reduction birth defects, Petitioners' proposition that the *Federal Rules of Evidence* no longer require general acceptance of scientific or experimental technique does not warrant serious consideration. It is, instead, an exercise drawn not upon an earnest debate over the law governing the admissibility of scientific evidence, but rather semantic hair-splitting designed to circumvent almost 80 years of thoughtful doctrine which protects the judicial factfinding process from becoming a scientific mockery.

The suggestion that *Frye* does not survive, or that there is a serious split in the Circuits regarding *Frye*, is premised on a linguistic distinction, which may have significance in other cases, but is entirely academic in Bendectin litigation. Circuits uniformly hold that trial courts must insist upon thresholds of reliability and acceptance of methodology before scientific testimony can be admitted.[12] Similarly, many state courts have found *Frye* useful in distinguishing legitimate science from unscrupulous hucksterism.

The *Federal Rules of Evidence* clearly provide for judicially created doctrines which aid the trial court in evaluating the admissibility of expert testimony. Rule 104(a) entrusts all preliminary questions concerning the admissibility of scientific evidence to the trial court, and expressly frees it from the rules of evidence in making that determination. Rule 403 authorizes the exclusion of evidence if there is a danger of confusion of the issues or misleading the jury. The teaching in *Frye*, and the other opinions which insist upon the satisfaction of thresholds of reliability as a prerequisite to the admissibility of expert testimony do nothing more than supply the analytic tools for evaluating proffered scientific evidence pursuant to the mandate of Rules 104(a) and 403.

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12. For Circuit opinions illustrating the uniformity of this doctrine, *see* Appendix, *infra*.

That this so-called split between the Circuits is nothing more than theoretical speculation is aptly illustrated by the practical application of the two dominant and purportedly competing standards: *Frye* and *Downing v. United States, supra.* As the Opinion notes, *Frye*, and its Ninth Circuit corollary, *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985), compel the conclusion that the Petitioners' proffered expert testimony be excluded. *Downing* requires exactly the same result as demonstrated by the District Court opinion in *DeLuca III*.

The Third Circuit reversed and remanded a prior ruling granting Merrell Dow's motion for summary judgment, instructing the District Court to reevaluate the plaintiff's evidence under *Downing*. *DeLuca II*, 911 F.2d 941, 955 (3rd Cir. 1990). Following a hearing held on five separate days, extensive post-hearing submissions of the parties, the District Court, applying the *Downing* standards, came to exactly the same conclusion as did Judge Gilliam in ruling on Merrell Dow's motion in the instant action. When applied to Bendectin, the *Downing* standard is properly understood as but a more particularized explanation of the more broadly stated *Frye* standard.[13]

At issue in *DeLuca III* was the admissibility of Dr. Done's opinion. Because the District Court could not ascertain Dr. Done's methodology, which could not be replicated, it concluded that it was novel. Dr. Done identified no specialized literature endorsing his methodology. Although Dr. Done had some scientific credentials, he had none in the field upon which he primarily relied in formulating his opinion, epidemiology. Dr. Done presented no evidence that his methodology has been put to *any* non-judicial

13. The *Downing* standard, to be applied in evaluating the reliability and soundness of a particular scientific methodology is: (1) the novelty of the technique in its relationship to more established modes of scientific analysis; (2) the existence of specialized literature; (3) the qualifications and professional stature of expert witnesses; (4) the non-judicial uses to which the scientific techniques are put; and (5) the frequency with which a technique leads to erroneous results. 753 F.2d 1238-1239.

use; rather, it was formulated exclusively for litigation purposes. The District Court found that his epidemiologic methodology yielded erroneous results so frequently that it is not helpful to the trier of fact. Applying all of the *Downing* factors, the District Court concluded that his methodology was both novel and unreliable, and relied upon only in litigation context. (*See also, Perry v. United States, supra,* 755 F.2d 888, 892 (11th Cir. 1985) ("The examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine.")).

Perhaps those trained in metaphysics will find the distinctions in the application of the *Frye* standard or the *Downing* standard intriguing; in Bendectin cases to date there has not been a bit of difference between them. If this Court is some day inclined to consider whether the Circuits are split on the issue of threshold reliability for the admission of expert testimony, it should consider the matter in a context where the so-called competing formulae make a difference, not in the context, such as is presented with Bendectin, where no matter what slant is put on the problem, the outcome is the same.

Contrary to Petitioners' suggestion, study of *United States v. Jakobetz*, 955 F.2d 786 (2nd Cir. 1992), concerning DNA identification evidence, provides no instruction as to the wisdom of granting the Petition. It is true that the Second Circuit criticizes *Frye*, and observes that it had abandoned it in favor of the approach expressed in *United States v. Williams*, 583 F.2d 1194, 1198 (2nd Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979). But analysis of the *Jakobetz* opinion teaches first that general acceptability is an important analytic tool in applying the *Williams* test, and second that the application of the *Williams* test to Bendectin would lead to exactly the same conclusion as the application of *Frye* or *Downing*.[14] The Second Circuit observed that within the *Williams*

14. The *Williams* factors to be utilized in determination of threshold reliability are: (1) the potential rate of error; (2) the existence and maintenance of standards; (3) the (Cont'd)

guidelines, general acceptability may be indicative of reliability and consequent probative value of the evidence. 955 F.2d 786, 796. The District Court in *Jakobetz* also relied upon whether the technique had been generally accepted by experts in the field before permitting the evidence to be admitted. *Id.* at 797. Lastly, the Second Circuit observed that the careful scrutiny by the District Court of the proffered evidence would satisfy not only *Williams*, but *Frye* as well. *Id.* at 799.

One cannot seriously entertain the suggestion that the application of the *Williams* standards would lead to a different result in a Bendectin case. This is especially true with respect to the risk of abuse standard. The scientific technique of unpublished result-oriented reanalysis of published epidemiological data to reach conclusions contrary to those found by the study's original authors would lend itself manifestly to abuse by credentialed hired guns willing to testify to any opinion convenient to the cause of their employer.

Chief Justice Taft cautions that the power of review on certiorari should be limited to cases where there is a real and embarrassing conflict of opinion and authority between the Circuit Courts of Appeal. *Layne & Bowler Corporation v. Western Well Works*, 261 U.S. 387, 392-393 (1923). As the foregoing illustrates, the Petitioners suggested conflict between the Circuits has no real significance in a Bendectin case. Each standard, whether *Frye*, *Downing*, or *Williams*, have at their root a basic screening function to protect the jury from confusing and misleading evidence,

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(Cont'd)
care and concern with which a scientific technique has been employed, and whether it appears to lend itself to abuse; (4) the existence of an analogous relationship with other types of scientific techniques and results that are routinely admitted into evidence; and (5) the presence of "fail safe" characteristics or the likelihood that potential inaccuracies will redound to the defendant's benefit rather than his detriment. *Williams*, 583 F.2d 1194, 1198-99, cited in *Jakobetz*, 955 F.2d 786, 794.

pursuant to the mandate of Rule 403, *Federal Rules of Evidence*. Just as all roads led to Rome, so do all of these variations on a theme lead to the same conclusion: In Bendectin litigation, expert testimony, unsupported by published epidemiological data, must be excluded.

II.

THE OPINION DOES NOT OFFEND ANY LIMITATION ON INHERENT JUDICIAL POWER REGARDING THE ADMISSIBILITY OF EXPERT TESTIMONY.

The Petition conjures up the specter of a judiciary run amok, capriciously ignoring the *Federal Rules of Evidence* and arbitrarily erecting artificial barriers to the admission of scientifically supportable expert testimony. In so doing, Petitioners misconstrue the Opinion, misread the *Federal Rules of Evidence*, and misunderstand the fundamental role of the trial judge in safeguarding a lay jury from the indefensible speculations of practitioners of mercenary science.

Contrary to the Petitioners' explicit assertion, the *Federal Rules of Evidence* did not abrogate the common law of evidence. Instead, they expressly recognize, through Rule 104(a), *Federal Rules of Evidence*, the duty of the trial judge to regulate the admission of evidence. In the exercise of that authority, the trial court neither abuses its inherent judicial power, nor ignores the substantive rights of litigants in diversity cases.

A. The Federal Rules of Evidence Do Not Abrogate the Federal Common Law.

The assertion that the *Federal Rules of Evidence* wipe clean the slate upon which the common law of evidence was, and is,

written lacks any support. While the rules must be construed like any other statute (*Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988)), statutory interpretation may not ignore decisional authority.

This Court recognized the viability of doctrines concerning the admission of evidence which antedate the *Federal Rules of Evidence* in *United States v. Abel*, 469 U.S. 45 (1984). Under consideration was the availability of cross-examination for bias under the *Federal Rules of Evidence*, which did not expressly provide therefor. In concluding that the rules were sufficiently flexible to accommodate cross-examination for bias, now Chief Justice Rehnquist cited with approval Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 Neb. L. Rev. 908, 915 (1978), which noted that ". . . [i]n reality, of course, the body of common law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers." *Id.* at 51-52. Thus, this Court has expressly acknowledged that authorities such as *Frye*, or other opinions articulating standards for the threshold of reliability for expert testimony, serve to guide trial courts in the application of the *Federal Rules of Evidence*, and do not, as Petitioners suggest, fade into jurisprudential anachronisms.

To apply well-settled standards of statutory construction, it is clear that if a rule reflects legislative intent to change the interpretation of a judicially created concept, Congress must make that intent specific. *Midlantic National Bank v. New Jersey Department of Envtl. Protection*, 474 U.S. 494, 501 (1986); *Harper v. Federal Land Bank of Spokane*, 878 F.2d 1172, 1176 (9th Cir. 1989). The party contending that legislative action changed settled law bears the burden of showing that the legislature intended such a change. *Green v. Bock Laundry Machine Company*, 109 S.Ct. 1981, 1991 (1989). Petitioners took no steps to

sustain this burden before either the District Court or the Ninth Circuit.[15]

In interpreting a statute or rule, the trial court is to consider the enactment in light of judicial concepts existing previously so to interweave new legislative policies with the inherited body of common law principles. *Moragne v. State Marine Lines Inc.*, 398 U.S. 375, 392 (1970); *Estate of Wood v. C.I.R.*, 909 F.2d 1155, 1160 (8th Cir. 1990). This is precisely the proper integration of the axiom expressed in *Frye* with the mandate of Rule 703, *Federal Rules of Evidence*.

Petitioners' citation to *Chambers v. NASCO, Inc.*, 111 S.Ct. 2123 (1991), is especially intriguing when one considers the interplay between the *Federal Rules of Evidence* and the federal common law. In *Chambers*, the majority, per Justice White, noted that the inherent judicial power to govern and regulate the proceedings before it compliments the various rules and statutes enabling the trial court to assess sanctions and penalties for misconduct, rather than having the rules swallow up the inherent power. ("At the very least, the inherent power must continue to exist to fill in the interstices." *Chambers*, 111 S.Ct. at 2134.) This observation echoes holdings of the Circuits regarding the relationship between the common law and the *Federal Rules of Evidence*. *See Werner v. Upjohn Company, Inc.*, 628 F.2d 848, 856 (4th Cir. 1980), *cert. denied*, 449 U.S. 1080 (1981) ("It is clear that in enacting the Federal Rules of Evidence Congress did not intend to wipe out the years of common law development in the field of evidence, indeed the contrary is true. The new rules contain many gaps and omissions and in order to answer these unresolved questions, courts certainly should rely on common law president. See Redden and Saltzburg *Federal Rules of Evidence Manual* 411-

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15. Of course, a fully developed record is essential to the proper exercise of this Court's discretion on certiorari. *Lytle v. Household Mfg. Inc.*, 110 S.Ct. 1331, 1336, n. 3 (1990).

413 (1975).") and *Cann v. Ford Motor Company*, 658 F.2d 54, 60 (2nd Cir. 1981).

Just as this Court recognized in *Chambers*, the complementary, not antithetical, relationship between inherent judicial power and rules governing the exercise of that power, so did the Opinion recognize the like dynamic between the common law of evidence and the *Federal Rules of Evidence*. Far from superseding all that has gone before, the *Federal Rules of Evidence* build upon the carefully constructed foundation of its common law antecedents.

B. The Federal Rules of Evidence Expressly Authorize Reliance On Judicially Created Doctrine Regarding The Inadmissibility Of Evidence.

The drafters of the *Federal Rules of Evidence* appreciated the need for flexibility on the part of the trial court in fulfilling its function as gatekeeper, barring the admission of plainly unreliable or untrustworthy evidence. Rule 104(a), expressly entrusts to the trial court all preliminary questions concerning the admissibility of evidence. As in other instances, the *Federal Rules of Evidence* draw instruction from this Court, which has consistently held that the district court enjoys wide discretion in the determination to admit or exclude expert testimony. *Hamling v. United States*, 94 S.Ct. 2887, 2903 (1974); *Salem v. United States Lines Company*, 82 S.Ct. 1119, 1122 (1962).

Since the *Federal Rules of Evidence* delegates to the trial judge the decision regarding the inadmissibility of evidence, unfettered by rules of evidence, it is clear that *Frye*, and other opinions expressing the requirement that expert testimony satisfy a threshold of reliability before its presentation to a jury, instruct the trial court in the exercise of this important duty. Thus, the *Federal Rules of Evidence* explicitly contemplate reliance on judicially

created doctrine in determining the admissibility of expert testimony.

The synergy of Rules 104(a) and 703 is naturally most frequently addressed in the opinions of district courts. In *Emigh v. Consolidated Rail Corp.*, 710 F.Supp. 608 (W.D. Pa. 1989), the court considered whether opinions of two non-treating physicians were admissible through plaintiff's experts in a Federal Employers' Liability Act suit alleging that decedent's death from lung cancer was due to work related asbestos exposure. In denying the motion for new trial, the court stressed its function under Rule 104(a) to preliminarily evaluate whether the reasonable reliance requirement of Rule 703 had been satisfied:

> However, we do not believe that the reasonable reliance requirement permits a court to relinquish its independent responsibilities to determine if the underlying source meets the most minimum standards of reliability and trustworthiness as a prerequisite to admissibility. See Fed. R. Evid. 104(a), 401, 403. J.Weinstein & M.Berger, *supra* at 703-2527. Although Rule 703 has greatly relaxed the law regarding the type of information on which an expert may base his opinion, it has not gone so far as to eliminate the requirement that an expert ground his opinion on reliable data rather than speculation. *Barrel of Fun, Inc. v. State Farm Fire and Casualty Co.*, 739 F.2d 1028, 1033 (5th Cir. 1984).

Id. at 612.

In considering evidence premised upon scientific technique or

methodology unsuitable for the proffered purpose, Rule 104(a) explicitly sanctions a trial court's dependence on opinions such as *Frye* in order to help it navigate treacherous waters, teaming with the confusing opinions of experts whose work is performed solely for the purposes of litigation. *See also, Stites v. Sunstrand Heat Transfer Inc.*, 660 F.Supp. 1516, 1523 (W.D. Michigan 1987) and *United States v. Pryba*, 678 F.Supp. 1225, 1232-1235 (E.D. Va. 1988).

The Opinion correctly, albeit implicitly, recognizes the pivotal role that Rule 104(a) plays when it comes to the admissibility of expert opinion based on scientific technique. It aptly places reliance upon Learned Hand's call for temperance in freely permitting every so-called expert to present his opinion to a lay jury, notwithstanding the fact that his opinion contravenes an essential teaching of his scientific community, and was created only due to the generosity of the litigant's subsidy:

> The serious objections are, first that the expert becomes a hired champion of one side. . . .
>
> Enough has been said elsewhere as to the natural bias of one called in such matter to represent a single side and liberally paid to defend it. Human nature is too weak for that; I can only appeal to my learned brethren of the long robe to answer candidly how often they look impartially at the law of a case they have become thoroughly interested in, and what kind of experts they think they would make, as to foreign law, in their own cases.

Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harvard Law Review 40, 50-53 (1902).

Far from proscribing judicial reliance upon the test expressed

in *Frye* and its progeny, the *Federal Rules of Evidence* instead encourage judicial use of such doctrines to help lead trial courts through the seemingly impassible maze of credentials, opinions, and unbridled self-interest that inevitably confounds the fact-finder in its weighing of expert testimony.

C. The Issues Addressed In Justice Kennedy's Dissent In Chambers Are Not Presented By The Petition.

In his dissent in *Chambers v. NASCO, supra*, 111 S.Ct. 2123, 2141, Justice Kennedy criticized the majority for failing to require adherence to express (whether via rule or statute) sanctioning provisions before reliance on inherent judicial power in assessing penalties against litigants and their counsel. Justice Kennedy's concern focused on judicial usurpation of both congressional rule making prerogative and state autonomy.

The Opinion offends none of the interests Justice Kennedy seeks to protect. As discussed above, the *Federal Rules of Evidence* expressly provide for the exercise of judicial judgment in the determination of preliminary facts governing the admissibility of evidence. Judicially-created doctrine requiring thresholds of reliability to be satisfied before the admission of expert testimony based upon unaccepted scientific methodology is entirely consistent with the general allocation of responsibility under the *Federal Rules of Evidence*.

The objective of *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938), is to discourage forum shopping and avoid inequitable administration of the laws. *Hanna v. Plumer*, 85 S.Ct. 1136, 1142 (1965). Neither is undermined by the Opinion. Although there may be semantic variations in the expression of the rule requiring that evidence satisfy a threshold of reliability, the bottom line is that all federal courts, following the *Federal Rules of Evidence*, require that such a threshold be satisfied. As *DeLuca III* illustrates, the

result is the same no matter which variation on the theme is applied; plaintiffs in Bendectin actions are unable to raise a triable issue of fact because of the absence of any published epidemiological data suggesting a link between it and limb reduction defects. Similarly, there is no unfairness in the administration of justice, where the outcome is uniform, notwithstanding the particular way in which a court may articulate its insistence that expert testimony be reliable.

The Circuits have consistently recognized that the *Federal Rules of Evidence*, and not the *Erie* doctrine, govern the admissibility of evidence.[16] In *Richardson*, 857 F.2d 823, 825, n. 9 (D.C. Cir. 1988), the D.C. Circuit rejected an argument similar to that advanced by Petitioners, noting that it was clear that *Erie* does not affect the application of the Federal Rules of Evidence, citing *Eli Lilly & Company v. Home Insurance Company*, 794 F.2d 710, 715 (D.C. Cir. 1986), *cert. denied*, 107 S.Ct. 940 (1986), and C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedures* §4512 (1982). The argument was once again rejected in *Ealy*, 897 F.2d 1159, 1163: "Contrary to the Ealys' assertion, however, this court is enforcing a procedural rule governing admissibility; it is not supplanting substantive state rules on the sufficiency of evidence."[17]

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16. This consensus echoes this Court's observation in *Hanna v. Plumer, supra*, 85 S.Ct. 1136, 1143-1144: "The Erie rule has never been invoked to void a Federal Rule. ... When a situation is covered by one of the Federal Rules, the question facing the court is a far cry from the typical, relative unguided Erie choice: The court has been instructed to apply the Federal Rule, and can refuse to do so only if the Advisory Committee, this Court, and Congress erred in their *prima facie* judgment that the Rule in question transgresses neither the terms of the Enabling Act nor constitutional restrictions. (Footnotes omitted.)"

17. This Court has denied repeated petitions for certiorari on the issue of the relationship between *Erie* and the *Federal Rules of Evidence*. *Eli Lilly & Company v. Home Insurance Company, supra*, 794 F.2d 710 (D.C. Cir. 1986), *cert. denied*, 107 S.Ct. 940 (1987); *United States v. Frazin*, 780 F.2d 1461 (9th Cir. 1986), *cert. denied*, *Miller v. United States*, 107 S.Ct. 142 and 107 S.Ct. 158 (1986); *Phillips Oil Co. v. O.K.C. Corp.*, 812 F.2d 265 (5th Cir. 1987), *cert. denied*, 108 S.Ct. 152 (1987).

California courts would not reach a different conclusion. The California Supreme Court has consistently relied upon *Frye* and has used it to exclude methodology not general accepted in the scientific community. *Huntingdon v. Crowley*, 64 Cal.2d 647, 656, 414 P.2d 382 (1966). Petitioners' citations to *People v. McDonald*, 37 Cal.3d 351 (1984); *People v. Pitts*, 223 Cal.App.3d 606 (1990); and *McCleery v. City of Bakersfield*, 170 Cal.App.3d 1059 (1985) are not germane. In each case, the mechanism of the particular phenomenon at issue was explained by the expert testimony. For example, in *McDonald* the expert testimony concerned psychological underpinnings of cross-racial identification. In the Bendectin litigation, however, the mechanism of how many birth defects occur is not known; hence, science is dependent upon epidemiology to confirm a causative link between an environmental factor (such as a medicine prescribed during pregnancy) and the defect. The California Supreme Court notes that when the scientific method is unproven, and ultimately unfounded, California courts are not constrained to admit testimony based upon it, simply because it is expressed by a witness with an academic pedigree. *People v. Shirley*, 31 Cal.3d 18, 53 (1982).

III.

THE OPINION'S INSISTENCE ON PEER REVIEW DOES NOT ABUSE JUDICIAL AUTHORITY.

The Petition criticizes the Opinion for a supposed judicially imposed requirement that renegade reanalysis of epidemiological data be subjected to peer review as a predicate to admissibility. In the unique circumstances of the Bendectin litigation, this condition is one of the few barriers that protects a jury from the unprincipled opinions of any venal technocrat willing to trade his credentials and opinions for whatever fee the market will bear. Especially when a disputed expert opinion bucks a nearly universal scientific consensus, the insistence upon peer review preserves the integrity

both of the trial, and the science there presented.[18]

Focus on what the Bendectin litigation is, and what it is not. The controversy surrounding Bendectin does not pit two schools of reputable scientific thought against one another, equally supported by independent sets of data, separately derived by disinterested observers. Rather, on one side of the Bendectin Armageddon is an array of independent scientific investigators who, via epidemiology, have scrutinized from 1976 to the present whether Bendectin causes limb reduction birth defects; without exception these investigators, despite every incentive to find a link between this popularly prescribed drug and birth defects, found absolutely none. This side of the struggle has consistently published, subjecting all of the data to the strictest standards of peer review. Lined up against these forces are a combination of doctors (medical and otherwise), veterinarians, and one epidemiologist, whose sole common denominator is that they have been retained by plaintiffs' attorneys representing clients alleging injuries due to exposure to Bendectin.[19] None of their work has been published, or

18. In the area of expert testimony, the requirement for peer review is invaluable. One cannot help but be reminded of Learned Hand's recognition that without such protections as peer review, a jury is unable, and indeed incapable to discern scientific truth from scientific fraud: "The trouble with all this is that it is setting the jury to decide, where doctors disagree. The whole object of the expert is to tell the jury, not facts, as we have seen, but general truths derived from this specialized experience. But how can the jury judge between two statements each founded upon an experience confessedly foreign in kind to their own? It is just because they are incompetent for such a task that the expert is necessary at all." *Hand, op.cit.*, at 53; cited in *Christophersen v. Allied-Signal Corp., supra*, 939 F.2d 1106, 1112.

19. In fact, Dr. Shanna Swan, the only epidemiologist retained on behalf of the petitioners, testified:

> Q. In fact, the reanalysis that you did was funded by plaintiffs' lawyers suing Merrell Dow; isn't that correct?
> A. That is correct and I should add that I so stated both times I presented the paper.

C.R. 162 Exhibit "12", Shanna Swan Trial Testimony, *Ealy v. Richardson-Merrell Inc.*, p. 3540, l. 20 - p. 3541, l. 3.

subjected to peer review; furthermore, all of their data is produced through unreliable scientific technique, which often cannot be replicated, performed at the request of litigants whose undisputed interest lies in finding a causative link between Bendectin and congenital abnormalities.

Under these circumstances, peer review and publication insulate the jury from the expert opinion formulated solely to satisfy the interests of those who paid for it. This protection is necessary because of the aura of apparent objectivity that surrounds scientific inquiry. Testimony that claims a scientific basis may carry undue weight with the trier of fact. *Sterling v. Velsicol Chemical Corp.*, 855 F.2d 1188, 1208 (6th Cir. 1988); *United States v. Brown*, 557 F.2d 541, 556 (6th Cir. 1977).

Petitioners suggest that far from being salutary, peer review is actually a device through which small-minded, conceited and jealous journal editors unfairly regulate the dissemination of scientific investigation. Before neither the District Court, nor the Ninth Circuit did Petitioners make any showing that the research upon which their champions rely suffered this fate. Instead, Petitioners apparently feel it is appropriate for this Court to judicially notice that peer review is the functional equivalent of some scholarly inquisition to burn the heretic and reward the devout.

In fact, peer review is far from an elitist barrier to the free flow of important scientific insights. It is considered vital to both scientific integrity and progress (Lock, "The State of Peer Review," *Peer Review and Scientific Publishing*, Council of Biology Editors, Inc., p. 30 (1990)). One author has written that it would be hard to imagine how society would get along without peer review. Relman, "How Good Is Peer Review," *New England Journal of Medicine*, Vol. 321, No. 12, p. 827 at 829. Stephen Lock, the editor of the British Medical Journal, explained the role of peer

review in the field of scientific inquiry in *A Difficult Balance*, Editorial Peer Review in Medicine (1985). He emphasizes that in order to be reliable, empirical observations and scientific theories must survive critical study in testing by other competent and disinterested people, and that publication plays a key part in this role. *Id.*, 1. Through the rigors of peer review, diagnostic standards for causation have been embraced by the scientific community. Included in these standards are such inquiries as: "Do other investigators consistently find the same result?" and "Does the association make epidemiological sense?" *Id.*, 118.

The antithesis of these rigorous epidemiological standards is, Dr. Lock has noted, a phenomenon called "pathological science," which has as its hallmark features present in the proffered testimony of the Petitioners' experts. *Id.*, 76-77. Among these characteristics are whether many measurements are necessary because of the very low statistical significance of the results, and whether the ratio of supporters to critics gradually falls to nil over time. Only through extensive, result-oriented reanalysis of published epidemiological data are the Petitioners' experts able to fashion any epidemiological inference regarding causation. Petitioners acknowledge that there are no peer reviewed published supporters of the hypothesis that Bendectin causes limb reduction defects.

Dr. Lock should not be understood as advocating the perfection of editorial peer review. However, he does maintain that it plays an essential role in medicine and science, since it is the best way of distinguishing between the promising and the meretricious. *Id.*, 129.

When confronted with a battle of peer reviewed vs. nonpeer reviewed experts, most courts choose the former and dismiss the latter. Consider, for example, *In Re Air Crash Disaster at New Orleans La.*, 795 F.2d 1230 (5th Cir. 1986), a wrongful death

action in which the verdict for the plaintiff was reversed because of the inherently incredible testimony of an economist on the issue of an anticipated inheritance:

> We know from our judicial experience that many such able persons present studies and express opinions that they might not be willing to express in an article submitted to a refereed journal of their discipline or in other contexts subject to peer review. We think that is one important signal, along with many others, that ought to be considered in deciding whether to accept expert testimony. Second, the professional expert is now commonplace. That a person spends substantially all of his time consulting with attorneys and testifying is not a disqualification. But experts whose opinions are available to the highest bidder have no place testifying in a court of law, before a jury, and with the imprimatur of the trial judge's decision that he is an "expert".

Id. at 1234.

The importance of peer review has been stressed in a number of contexts outside the ambit of Bendectin litigation. *See In Re Agent Orange Product Liability Litigation, supra*, 611 F.Supp. 1223, 1242 (E.D.N.Y. 1985), *affirmed on other grounds*, 818 F.2d 187 (2d Cir. 1987), *cert. denied, sub. nom Lombardi v. Dow Chemical Company*, 487 U.S. 1234 (1988); *Kubs v. United States*, 537 F.Supp. 560, 562 (E.D. Wis. 1982); *Kilburn v. United States*, 938 F.2d 666, 673 (6th Cir. 1991).

The Opinion properly relies upon the requirement for peer review expressed in the reported decisions of sister circuits. For

example, in *Richardson*, 857 F.2d 823 (D.C. Cir. 1983) the D.C. Circuit affirmed the granting of judgment notwithstanding the verdict, noting:

> The district court observed that Dr. Done had performed none of his own studies nor published his criticisms of the studies performed by others, but nonetheless testified in contradiction to 'not only Dr. Seltser (defendant's expert) but to the findings of all those researchers who have studied and published in the 20 odd years since the investigation of Bendectin began.'

Id. at 826. The *Richardson* opinion goes on to observe that uniquely in the context of Bendectin litigation, the law now has the benefit of 20 years of scientific study, and the published results of such work must be given their just due. *Id.* at 832.[20]

In *Lynch v. Merrell-National Laboratories, supra*, 830 F.2d 1190, 1194 (1st Cir. 1987), the summary judgment in favor of the defendant was affirmed, just as it was in this case:

> The first (epidemiologic studies) began in 1963; studies are still being published in 1986. No correlation, much less a causal connection, has been demonstrated between the use of Bendectin and limb reduction. . . . A new study coming to a different conclusion in challenging the consensus would be

20. *Accord, Ealy*, 897 F.2d 1159, 1162. ("Unlike the circumstances of *Ferebee* [*v. Chevron Chemical Company*, 736 F.2d 1529 (D.C. Cir. 1984)], the body of *published* epidemiological opinions on the subject at hand is extensive, indeed massive, and all such opinions point to the same conclusion.")

> admissible evidence. Without such a study, there is nothing on which expert opinion on Bendectin as a cause may be based. The plaintiffs offered no new study.

Id. at 1193-1194.

In *Brock*, 874 F.2d 307 (5th Cir. 1989), the Fifth Circuit criticized plaintiff's biostatistics expert because he had not published his opinion or conclusion for the purposes of peer review. The opinion counseled that courts must nonetheless be especially skeptical of medical or other scientific evidence that has not been subjected to thorough peer review. *Id.* at 313.

The Petition falsely implies that the Opinion artificially bars unorthodox but unpublished scientific theories from the courtroom. The Opinion holds that when published data is to be reanalyzed for litigation to reach a result antithetical from that intended by its authors, then that reanalysis must be peer reviewed to be admissible. This result is sound, consistent with long-standing authority, and does not warrant further review or comment by this Court. As discussed above, the *Federal Rules of Evidence* expressly provide for the exercise of judicial judgment in the determination of preliminary facts governing the admissibility of evidence. Judicially created doctrine requiring thresholds of reliability to be satisfied before the admissibility of expert testimony based upon scientific methodology not widely accepted in the scientific community is entirely consistent with the general allocation of responsibility under the *Federal Rules of Evidence*.

CONCLUSION

The Petition should be denied. The energies of this Court should only be marshalled to consider issues of broad application. The stage on which the Bendectin litigation is played out is peculiar to itself; no other theater presents a drama where the line between fact and illusion is so clearly drawn. Only Bendectin plaintiffs and their expert footmen resist that concurrence of the scientific community that Bendectin does not cause limb reduction birth defects. The Circuits uniformly require that expert testimony satisfy a threshold of reliability; no matter how that threshold is articulated, the expert testimony proffered by Petitioners cannot pass muster. Rules relied upon in Bendectin litigation are sound in that context, but not necessarily so in all others. Scrutiny by this Court of these issues is unwarranted.

Respectfully submitted,

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APPENDIX - ILLUSTRATIVE CIRCUIT OPINIONS

FIRST CIRCUIT: *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190, 1194-95 (1st Cir. 1987) (expert testimony inadmissible after a critical analysis of experts' methodologies and the lack of peer review of proffered studies).

SECOND CIRCUIT: *United States v. McBride*, 786 F.2d 45, 49 (2nd Cir. 1986) ("expert testimony must be based upon a reliable area of expertise, as has come to be embodied in the rule associated with *Frye v. United States*.") But *cf. United States v. Williams*, 583 F.2d 1194 (2nd Cir. 1978), *cert. denied, Williams v. United States*, 439 U.S. 117 (1979) and *United States v. Jakobetz*, 955 F.2d 78 (2nd Cir. 1992).

THIRD CIRCUIT: *DeLuca v. Merrell Dow Pharmaceuticals Inc.*, 911 F.2d 941, 956 (3rd Cir. 1990) ("The district court is permitted to identify relevant scientific communities and make determinations about the degree of acceptance of [plaintiff's experts] methodology within those communities"). It should be noted that although the Third Circuit does not follow *Frye*, the difference between its test and *Frye* is explained in the Third Circuit opinion in *United States vs. Downing*, 753 F.2d 1224, 1238. "The reliability inquiry that we envision is flexible and may turn on a number of considerations, in contrast to the process of scientific 'nose-counting' that would appear to be compelled by a careful reading of *Frye*."

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"Thus, we expect that a technique that satisfies the *Frye* test usually will be found to be reliable as well. On the other hand, a known technique which has been able to attract only minimal support within the community is likely to be found unreliable.").

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FOURTH CIRCUIT: *Ellis v. International Playtex Inc.*, 745 F.2d 292, 304 note 15(4th Cir. 1984) (continuing to recognize the validity of the *Frye* test).

FIFTH CIRCUIT: *Christopherson v. Allied Signal Corp., et al.*, 939 F.2d 1106 (5th Cir. *en banc* 1991), *cert.denied*, 112 S.Ct. 1280 (1992) (District Court was within its discretion in concluding, albeit implicitly, [the experts] testimony failed to meet . . . the *Frye* test.)(The *Federal Rules of Evidence* combined with *Frye v. United States*, 293 F. 1013 (D.C.Cir. 1923), provide a framework for trial judges struggling with proffered expert testimony.) *See also, Barrel of Fun Inc. v. State Farm Fire & Casualty Co.*, 739 F.2d 1028 (5th Cir. 1984) (using *Frye* test to hold inadmissible a voice stress analysis process).

SIXTH CIRCUIT: *United States v. Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986) ("[this Circuit] still predicate[s] the admission of scientific evidence on general acceptance in the community").

SEVENTH CIRCUIT:*United States v. Smith*, 869 F.2d 348, 351 (7th Cir. 1989) ("this Circuit has continued to affirm (and to apply) the *Frye* standard").

EIGHTH CIRCUIT: *United States v. Two Bulls*, 918 F.2d 56, 60 n.7(8th Cir. 1990) (refusing to reject use of *Fry* in evaluation of "the admissibilily of any questionable opinion evidence").

NINTH CIRCUIT: *United States v. Gillespie*, 852 F.2d 475, 481-82 (9th Cir. 1988) (criminal conviction reversed because testimony of child therapist relating to child's behavior with anatomically correct dolls did not satisfy the *Frye* standard). *See also, Dang Vang v. Vang Xiong X. Toyed*, 944 F.2d 476, 482 (9th Cir.

Appendix

1991) (the Court acknowledged the use of *Frye* in the Ninth Circuit; however, the test was inapposite because the case did not involve novel scientific technique).

TENTH CIRCUIT: *Head v. Lithonia Corp. Inc.*, 881 F.2d 941, 943-44 (10th Cir. 1989) (expert opinion based on topographical brain mapping excluded because technique was relatively experimental and not accepted by the scientific community).

ELEVENTH CIRCUIT: *United States v. Piccinonna*, 885F.2d 1529,1531 & 1536 (11th Cir. 1989) (*Frye* limits, though does not bar, the admission of polygraph evidence in criminal trials).

D.C. CIRCUIT: *Kropinski v. World Plan Executive Council - U.S.*, 853 F.2d 948, 956 (D.C. Cir. 1988) ("We have recently held that *Frye is* still the law in this circuit."(citing *United States v. Shorter*, 809 F.2d 54, 59-61 (D.C. Cir.) *cert. denied*, 484 U.S. 817 (1987)).